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| 10/590,531 | 08/24/2006 | Rex J. Kuriger | 247082-09/USPX (MSE-2685) | 9794 |
| 71331 | 7590 | 05/25/2010 | EXAMINER | |
| NIXON PEABODY LLP 300 S. Riverside Plaza, 16th Floor CHICAGO, IL 60606-6613 | | | EISEMAN, ADAM JARED | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/590,531

Applicant(s)

KURIGER ET AL.

Examiner

ADAM J. EISEMAN

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/19/2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI.08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is responsive to applicant's amendments and arguments/remarks filed on 2/19/2010.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-7 and 10-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas (US 5,951,492 referenced in previous action) in view of Dosmann (US 2003/0171696) and Roe et al (US 2004/0127818).

Douglas discloses an apparatus for lancing the skin of a test subject and collecting a body fluid sample from the lanced site comprising: A body (element 26) having an open end (see figure 1); a disposable element comprising a lancing needle for piercing the skin and a capillary tube for collecting the body fluid from the lancing site (column 5, lines 36-43); a lancing mechanism for coupled to the needle adapted to move the lancet between a retracted position and a lancing position (column 5, lines 25-35); a mechanism for moving the capillary tube toward the lancing site for collecting a body fluid (column 5, lines 59-67); an outer end cap (element 24) having a first end couple to the open end of the body and a second end for contacting the skin of the subject, the outer end cap having an aperture that the tip of the lancet enters when in the lancing position, and a wall extending between the first and second end (column 5, lines 44-58; figures 1 and 2); and an inner end cap (element 66) disposed within the outer end cap having a first end couple to the body and a second end forming a second

aperture that the lancet enters when lancing, the second end adapted to contact the skin of the test subject when in the collecting position, the wall of the outer end cap extending farther towards the skin than the inner end cap during lancing such that the skin of the subject is drawn inside the outer end cap and contacts the inner end cap (see figures 5 and 6).

However, Douglas does not disclose a hollow lancet for lancing and collecting the fluid sample wherein the interior of the hollow lancet forms a channel for moving the fluid sample from the tip to the reaction area; that the lancing mechanism provides for a collecting position; or that the outer and cap and the inner end cap remain in contact with the skin in the lancing position to assist in sample formation and collection..

Dosmann teaches an optical format for lancing the skin for collecting a body fluid sample from the lanced site comprising a hollow lancet (element 10) having a tip adapted to puncture skin and collect body fluid (paragraphs [0003]-[0004]; figures 1 and 2); the interior of the hollow lancet forming a channel (element 13) for moving a fluid sample from the tip to a reaction area (paragraph [0014]). The body fluid is drawn through the channel using capillary action or vacuum assisted capillary action (paragraph [0014]). Furthermore this optical format and integrated lance includes a viewing window to allow optical analysis of the sample by transmission spectrometry by passing a beam of light through the lance viewing windows to a detector (paragraphs [0004] and [0014]). The lancet provides for significantly less pain, high probability of blood harvesting and improved overall test time by integrating the lance, harvest and analysis operations (abstract).

Roe teaches a tip design comprising an outer end cap for contacting the skin (element 46) and an inner end cap (element 82) disposed within the outer end cap wherein the outer end cap and the inner end cap remain in contact with the skin in the lancing position in order to assist in sample formation and collection (see figure 2, both end caps are in contact with the skin during the lancing position).

Regarding claims 1-7 and 10-35; it would have been obvious to one of ordinary skill at the time of the invention to substitute Douglas' disposable elements comprising separate needle and capillary tube connected to a test element with Dosmann's singular hollow lancet for lancing the skin and collecting fluid through the interior of the lancet in order to improve test time by integrating the lance, harvest and analysis operation as taught by Dosmann. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Douglas' end caps to both remain in contact with the skin during the lancing position as taught by Roe to assist in sample formation and collection.

Further regarding claims 1-7 and 10-35; Douglas teaches that the capillary tube is movable to a collecting position in order to collect the body fluid from the lancing area. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Douglas' lancing mechanism to include a collecting position in order to draw the fluid into the channel formed in the hollow lancet of a Douglas/Dosmann/Roe combination.

Further regarding claims 2, 3, 10 and 29-32; Dosmann discloses the lancet defined by a square, fused silica capillary tube (paragraph [0010]).

Further regarding claim 4-6; Dosmann discloses the use of a vacuum around the lancing area to enhance blood flow (paragraph [0004]). It would have been obvious to one of ordinary skill in the art at the time of the invention that a vacuum used in the Douglas/Dosmann/Roe combination apparatus when the outer end cap is in contact with the skin would evacuate the air from the inner and outer ends caps and thusly create a vacuum that would position the skin of the test subject against the second end of the inner end cap.

Further regarding claims 5 and 6; it would have been obvious to one of ordinary skill in the art at the time of the invention to use known methods of applying a vacuum in blood collection devices including use of a diaphragm or bellows.

In regards to claim 7; Dosmann discloses using a light source for illuminating the reaction of the reagent and analyte in the fluid sample and a light detector for detecting light transmission through the reaction (paragraph [0014]).

Regarding claim 11; it would have been obvious to one of ordinary skill in the art at the time of the invention to have the retracted and collecting positions of a Douglas/Dosmann/Roe combination be substantially the same in order to simplify the lancing mechanism so that it only has two positions instead of three (since the collecting and retracted position would be the same).

Further regarding claims 12-34; the method as claimed would define the obvious use of a Douglas/Dosmann/Roe combination in view of Dosmann's disclosure on the method of optically analyzing a body fluid collected from a puncture site (paragraph [0014]) and Douglas' disclosure of how the lancing body and mechanism works.

In regards to claim 18 and 28; it would have been obvious to one of ordinary skill of optical analysis to determine the start time of a colorimetric reaction based on the light transmitted through the lancet.

Further regarding claim 35; Douglas shows that the inner end cap does not extend beyond the outer end cap in the retracted, lancing and collecting positions (figures 1-6). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention that the inner end cap remained entirely disposed within the outer end cap in all positions.

Response to Amendment

The applicant's amendments and arguments/remarks have been fully considered but are moot in view of the new grounds of rejection presented above.

Furthermore, the applicant argues that it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Douglas by Dosmann as rejected because Dosmann's lance only has a single position while Douglas has an extending and retracting lance; and that Dosmann discloses a disposable optical integrated lance whereas Douglas discloses a reusable lancing device having a disposable lancet, capillary tube and test strip. The applicant's arguments are found to be non persuasive. Firstly, as cited in the rejection using the Douglas/Dosmann/Roe combination above, Douglas's disposable lance, capillary tube and test element are being substituted with Dosmann's integrated hollow lancet. Therefore the substitution of one Douglas's disposable elements for another equal disposable element would have been obvious and practical (thus substituting a disposable lancet, capillary tube and test

strip with a equally disposable lancet having an integral test capillary channel which can be in contact with a disposable test strip is obvious). Secondly, it would have been obvious to one of ordinary skill in the art at the time of the invention that the Dosmann lancet could be carried through Douglas' lancing procedure having Dosmann substituted for Douglas' lancet without compromising the ability of Dosmann's integrated lancet to perform the desired function. Essentially, Dosmann's lancet is capable of moving through different lancing movements, Dosmann discloses the lance is capable of entering the skin and exiting the skin (thus the position is changed at some point, and thus possible for use with Douglas).

Furthermore the applicant argues that the Douglas/Dosmann/Roe references teach away from each other and change the principle of operation of the Douglas reference. The examiner finds the argument non persuasive. Douglas teaches drop sensing mechanism for detecting if there is adequate blood for testing. Further more it teaches the use of stimulator sleeve to express blood from the incision in order to have adequate blood for testing. Thus the examiner believes it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the inner sleeve and outer sleeve to be in simultaneous contact in order to both express the blood and sense if the blood has been expressed to an adequate amount for testing.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM J. EISEMAN whose telephone number is (571)270-3818. The examiner can normally be reached on Monday-Friday 9:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AE
5/21/2010
/A. J. E./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736